Remarks

Claims 4—10 have been objected to as being in improper for including multiple dependent claims that depend from multiple dependent claims. Applicant directs the examiner to Applicant's preliminary amendment filed 26 April 2006 in which the multiple dependencies of claims 4, 5, 7, 9 and 10 were removed. Applicant's election filed 30 September 2008 noted that amendments to claims 4, 5, 7, 9 and 10 were previously presented and such claims did not include multiple dependencies as amended. Accordingly, Applicant request withdrawal of the objection to claims 4—10.

Claims 1—3 have been rejected as anticipated by Freed. Freed, however, fails to teach or describe every limitation of claim 1. Specifically, Freed does not teach, describe or suggest

> a second gas-line part adapted to be part-implanted and part-external and having a first (external) end adapted for sealing connection to an external driver and a second (implanted) end adapted for removable sealing connection with the connection fitting on the second end of the first gas-line part, wherein the connection between the first gas-line part and the second gas-line part is adapted to be positioned fully within the body of the patient in spaced relation with an exit site in the body of the patient through which the second gas-line part is adapted to pass

as claimed in claim 1. The Examiner asserts that Freed discloses a "second gas-line 18 adapted to be part-implanted and part-external ... and a second (implanted end adapted for removable sealing connection with the connection fitting 16 on the second end of the first gas-line part." Applicant has carefully reviewed Figures 1, 3 and 4, and the specification at columns 3, 4 and 9

and respectfully submit that the Examiner's characterization of Freed is incorrect. Freed describes his device and its installation as follows:

> About one week before the implantation of the blood pump, the PAD will be implanted. In this surgical procedure, a transverse skin incision is made at the level of L_{1-2} of the left hypogastric region. From this incision a subcutaneous pocket 10 cm in diameter is created, and a circular incision is made in the skin covering the pocket. **The PAD is inserted through the transverse incision into the subcutaneous pocket and exposed through the circular incision.** Care is taken to avoid contact with the PAD fibroblast coating. The pocket is closed using Prolene sutures. (Col. 3, lines 29—38).
>
> The PAD [12] has two main parts as illustrated in FIG. 3: (1) an implanted, 0.75" diameter cylindrical neck with a flexible, cloth-covered flange at a base 16, precoated with fibroblasts and implanted about a week before blood pump insertion, and positioned near the patient's navel, with the flange under the skin, and inside the neck is a replaceable turret; and (2) an **external, detachable part 18 which connects the PAD to the drive unit 14.** (Col. 4, lines 27—34).
>
> Recall that the PAD 12 has three main parts as illustrated in FIG. 4: (1) a **cylindrical neck 20 with a flange 22 at the bottom, implanted so that the neck protrudes through the skin 24**; (2) a replaceable turret 26 inside the neck; and (3) **an external part 18,** which connects to the drive unit's external drive line. The PAD is positioned near the patient's navel. During the implantation procedure, an **internal drive line 28** from the blood pump and the pacemaker leads 30 from the epicardium are **connected to the implanted part of the PAD** as illustrated prior to implantation in FIG. 5. (Col. 9, lines 45—54).

It is clear from Freed's description that the "second gas-line part 18" referred to by the Examiner is only external to the patient and not "adapted to be part-implanted and part-external" as claimed. In addition, Freed's PAD 12, which includes a flange 16 in Figure 3 and flange 22 in Figure 4 and operates as the connector between the "second [external] gas-line 18" and "internal drive line 28", is implanted at the exit site of the patient where it extends through the surface of the skin 24. The PAD[/connector] 12 is clearly not "positioned fully within the body of the patient in spaced relation with an exit site in the body of the patient through which the second gas-line part is adapted to pass" as claimed.

The claimed configuration, which includes a connection between the two gas-lines being wholly implanted within the body of the patient and spaced from the exit site, advantageously results in only a simple lead projecting through the skin of the patient at the exit site and tends to reduce the occurrence of infection at the exit site as a result. However, if the exit site were to become infected, the claimed configuration advantageously enables the second gas-line to be removed from the patient after disconnection from the first gas-line and, because the first gas-line and connector are positioned wholly within the patient and spaced apart from the infection zone, the configuration enables the first gas-line to be connected to a new, sterile second gas-line that can be brought out of the body at a new position.

In contrast, if the Freed device becomes infected, the connector (PAD 12) must be surgically removed, which can complicate the treatment of the infection. Moreover, if the Freed device becomes infected, the internal lead, i.e., internal drive line 28, which extends from the connector, i.e. PAD 12, at the exit site and up to and including the active component of the device, would need to be removed because it would be impossible to sterilize the lead in-situ.

Accordingly, Freed fails to anticipate claim 1 and claims 2—10 by virtue of their dependence upon claim 1. It is believed that the present application is in condition for allowance and a favorable action is respectfully solicited.

The Commissioner is authorized to charge a one month fee of **$60.00** to deposit account No. 15-0665 and any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,
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